UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

OKLAHOMA POLICE PENSION FUND AND RETIREMENT SYSTEM, et al.,	
Plaintiffs,	
- against -	19 Civ. 3354 (VM)
TELIGENT, INC., et al.,	**DECISION AND ORDER**
Defendants.	

VICTOR MARRERO, United States District Judge.

Plaintiff Oklahoma Police Pension Fund and Retirement System ("Oklahoma Police"), on behalf of itself and all others similarly situated, brings this action against defendants Teligent, Inc. ("Teligent" or the "Company") and Jason Grenfell-Gardner ("Grenfell-Gardner," and together with Teligent, "Defendants"). Oklahoma Police purports to represent a class consisting of all persons who purchased or otherwise acquired Teligent common stock between March 7, 2017 and November 6, 2017, inclusive and who were damaged thereby (the "Class Period"). The Second Amended Complaint alleges that during the Class Period, Defendants made materially false and misleading statements in violation of Section 10(b) of the Securities Exchange Act of 1934 (the "Exchange Act") ("Section 10(b)") and Securities and Exchange Commission ("SEC") Rule 10b-5 ("Rule 10b-5"). Oklahoma Police also alleges that Grenfell-Gardner violated Section 20(a)

("Section 20(a)") of the Exchange Act. (See "SAC," Dkt. No. 39, ¶¶ 177-94.)

Before the Court are the pre-motion letters submitted by the Defendants seeking leave to file a motion to dismiss the SAC. Defendants notified Oklahoma Police of their intent to seek permission to file a motion to dismiss the SAC pursuant to Federal Rule of Civil Procedure 12(b)(6) ("Rule 12(b)(6)") on January 15, 2020. Defendants argue the SAC is deficient because it fails to plead that Defendants either made misleading statements or did so with scienter, and also fails to plead loss causation. (See "Motion," Dkt. No. 40.) By letter dated January 22, 2020, Oklahoma Police responded to the Motion and argued that the SAC is well-pled. (See "Opposition," Dkt. No. 43.) By letter dated January 28, 2020, Defendants replied to the Opposition and reiterated their intent to file a motion to dismiss. (See "Reply," Dkt. No. 41.)[1]

[1] The parties previously exchanged pre-motion letters regarding earlier versions of the complaint. The initial complaint in this action was filed on April 15, 2019. (See Dkt. No. 1.) Oklahoma Police filed an amended complaint on September 13, 2019. (See "Amended Complaint," Dkt. No. 32.) By letter dated October 25, 2019, Defendants notified Oklahoma Police of their intent to file a motion to dismiss the Amended Complaint. (See "October 25 Letter," Dkt. No. 33.) By letter dated November 5, 2019, Oklahoma Police responded. (See "November 5 Letter," Dkt. No. 37.) While these letter motions were effectively mooted by the filing of the Second Amended Complaint, the Court has reviewed and, to the extent relevant, considered the arguments made in the October 25 Letter and the November 5 Letter in reaching its decision here.

The Court now construes Defendants' Motion and Reply as a motion by Defendants to dismiss the SAC pursuant to Rule 12(b)(6) (the "Letter Motion").[2] For the reasons set forth below, the Letter Motion is DENIED.

I. BACKGROUND[3]

A. FACTUAL BACKGROUND

This case revolves around a pharmaceutical company, Teligent; its CEO, Grenfell-Gardner; and their allegedly false and misleading statements regarding Teligent's compliance with Food and Drug Administration ("FDA") regulations and ability to develop and submit Abbreviated New Drug Applications ("ANDAs") to the FDA. The SAC alleges that Teligent, while touting an increased number of ANDAs, achieved that increase only by cutting corners and systematically failing to comply with the relevant regulations, including by failing to have or follow required standard operating procedures ("SOPs") and controls, failing to investigate out-of-specification ("OOS") test results as required, failing to validate testing methods, and failing to

[2] Kapitalforeningen Lægernes Invest v. United Techs. Corp., 779 F. App'x 69, 70 (2d Cir. 2019) (Mem.) (affirming district court ruling deeming exchange of letters as motion to dismiss).

[3] Except as otherwise noted, the factual background below derives from the SAC and the facts pleaded therein, which the Court accepts as true for the purposes of ruling on a motion to dismiss. See infra Section II.A. Except where specifically quoted, no further citation will be made to the SAC. Unless otherwise noted, when quoting the SAC, all internal quotation marks are omitted.

store required records and data. The SAC alleges that Defendants concealed the fact that Teligent had received letters from the FDA about these compliance failures, known as "483 letters," in September 2016 ("September 2016 483 Letter") and October 2017 ("October 2017 483 Letter").[4] Plaintiff alleges that because of Teligent's compliance failures, its ANDA submissions slowed to a halt during and after the Class Period, to the point where it submitted only three ANDAs in 2018 (from a high of fifteen in 2015) and had filed none in 2019 as of the filing of the SAC in early December. After Teligent disclosed its manufacturing challenges and pipeline delays on November 6, 2017, its stock price dropped by 43.62 percent.

1. Shift in Teligent's Business Model

Oklahoma Police ties the allegations of the SAC to a change in Teligent's business model overseen by Grenfell-Gardner. Teligent develops generic treatments, primarily topical ointments and lotions. Grenfell-Gardner joined Teligent as CEO in July 2012, and in April 2014, he announced that he was accelerating the Company's shift in focus from contract services (that is, manufacturing pharmaceutical products for third-party customers) to developing its own

[4] Teligent received a third Form 483 in May 2019 ("May 2019 483 Letter").

generic products through research and development ("R&D"). Specifically, Grenfell-Gardner set "three key goals" for the Company: "revenue growth between 40% and 45%; . . . at least 10 ANDA filings with the FDA for generic topical pharmaceutical products; and . . . maintaining profitability in 2014, while at least doubling [Teligent's] R&D spend[ing]." (SAC ¶ 24.)

Generic drugs may be marketed only if the maker demonstrates to the FDA that it has complied with FDA regulations to ensure the safety and effectiveness of the treatment. ANDA submissions generally rely on nonclinical laboratory tests that establish that the generic drug has the same characteristics as the treatment on which it is based and can be consistently produced. As Oklahoma Police points out, the FDA does not simply accept any data submitted in support of an ANDA; rather, the FDA will refuse to approve the ANDA if it finds that the "methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug product are inadequate to ensure and preserve its identity, strength, quality, and purity." 21 C.F.R. § 314.127(a)(1)). The Code of Federal Regulations sets forth certain minimum methods and controls that drug makers must follow, collectively referred to as

"Good Manufacturing Practice" ("GMP") or "current Good Manufacturing Practice" ("cGMP"), and additional methods and controls for nonclinical laboratory studies, collectively referred to as "Good Laboratory Practice" ("GLP"). Furthermore, generic drug makers must have and follow appropriate SOPs.

2. Alleged Failure to Comply with FDA Regulations

Oklahoma Police alleges that Teligent failed to comply with the relevant FDA regulations. The SAC alleges that as R&D costs increased, due to the Company's attempts to improve its pipeline of ANDA submissions, the Company cut corners. Oklahoma Police relies on two main sources for these allegations: a confidential witness and the results of FDA inspections.

First, Oklahoma Police incorporates into the SAC the allegations of a confidential witness ("CW 1") who worked for Teligent as an investigations scientist in the quality control department ("Quality Control") and who reported to two people who both reported directly to Grenfell-Gardner. According to the SOP within the industry, Quality Control should try to close investigations into OOS results within 30 days, but CW 1 states that this standard was impossible for Teligent to achieve because the Quality Control department

was under-resourced and he or she "often had between 30 and 40 open investigations at any one time." (SAC ¶ 38.) ANDAs cannot be filed with the FDA until OOS results are closed, and CW 1 states that he or she was pressured to close investigations and that "management regularly decided to declare investigations 'closed' prematurely." (SAC ¶ 39.) Specifically, CW 1 states that out of the 400 or so investigations CW 1 worked on, CW 1 felt pressured to close "dozens" of investigations before CW 1 was comfortable doing so. (SAC ¶ 65.) For example, in one case, CW 1 was pressured to close a case by declaring the result to be due to an "undetermined error" by the analyst, instead of proving this conclusion. (SAC ¶ 67.) CW 1 recalled that in January 2018, when he or she asked for more staff and resources to help complete investigations in time, the Vice President of Quality Control told CW 1 that such increase would not happen.

Second, Oklahoma Police relies on the findings of a series of FDA investigations at Teligent's headquarters in Buena, New Jersey (the "Buena Facility"), where the Company had its executive offices along with facilities for R&D, nonclinical laboratory testing, and manufacturing. The first investigation, in September 2016, resulted in Defendants receiving the September 2016 483 Letter, followed by an

Establishment Inspection Report ("EIR") that elaborated on the findings in the September 2016 483 Letter and an additional follow-up letter emphasizing certain compliance issues. In general, Forms 483 are letters issued to management at the end of an inspection when the investigator has observed conditions that may constitute violations of the applicable statutes and regulations. Each observation must be "clear, specific and significant." (SAC ¶ 46.) The September 2016 483 Letter, which followed an inspection by the Office of Study Integrity and Surveillance in the FDA's Division of Generic Drug Bioequivalence Evaluation, contained the following observations:

> (1) Teligent "did not randomly select and retain reserve samples" from the product samples it was testing to show bioequivalence,
> (2) The "drug accountability records" for the product samples used in bioequivalence studies "were insufficient to reconstruct the receipt, storage, handling, and use of these products,"
> (3) The method for measuring certain "concentrations in study samples used only a single concentration . . . that was not representative of the range of . . . concentrations" at issue and "no separate quality control samples were used to evaluate [the] accuracy and precision" of the test,
> (4) The "[q]uality control samples representing the range" of certain concentrations were "not included in the HPLC [high-performance liquid chromatography] analysis," which identifies and quantifies the component parts of a material, and
> (5) The stability studies on certain solutions were "not evaluated with a fresh calibrator solution," meaning that Teligent did not run quality control checks against the full range of characteristics of the solution and

> did not refresh the calibrator solution with samples representing that full range.

(SAC ¶¶ 49-50.)

The EIR that followed the September 2016 483 Letter concluded, under the heading of "Facilities and Site Operations," that "[t]he SOP program is not adequate and current to ensure quality in analytical operations and the generated in-vitro study data" and that "[t]he sample receipt and accountability processes were not adequate to ensure the integrity of the sample usage during the study." (SAC ¶ 51.) The EIR also found that "[t]here were no SOPs for reserve samples, sample accountability and storage of drug products." (SAC ¶ 51.) Oklahoma Police alleges that the observations in the September 2016 483 Letter and the EIR that followed implicated GMP, GLP, and other regulations.

Teligent responded to the September 2016 483 Letter and acknowledged that it had used "inappropriate" test methods, had "failed to use quality control samples," and had a "gap" in its SOPs. (SAC ¶ 54.) Teligent promised to fix its compliance failures.

The FDA replied on February 21, 2017 by letter addressed to Grenfell-Gardner ("February 21, 2017 Letter"), emphasizing its observation of "objectionable conditions" and its conclusion that Teligent had "not adhere[d] to the applicable

statutory requirements and FDA regulations governing the conduct of BE [bioequivalence] studies," and emphasizing that Teligent had "failed to meet the regulatory requirements for retention of reserve samples for bioavailability or bioequivalence studies." (SAC ¶ 56.) The FDA noted that its findings "raise[d] concerns about the validity and integrity of the studies conducted at [Teligent's] study site." (SAC ¶ 56.)

The FDA also inspected the Buena Facility in October 2017. Following this inspection, the FDA issued the October 2017 483 Letter and another EIR. The October 2017 483 Letter contained the following observations:

> (1) Teligent failed to "handle materials in a manner to prevent contamination" during a 2016 contamination incident,
> (2) In three ANDAs, two dating to 2015 or 2016, Teligent "failed to conduct investigations properly"; for OOS tests, the "[i]nvestigation into [such] failures are not performed or not performed adequately,"
> (3) In three ANDAs, all dating to 2015 or 2016, the suitability of Teligent's test methods used to undertake certain required tests "have not been established,"
> (4) In an incident involving "submission batches" of a potential product provided to the FDA in support of an ANDA, Teligent's "[t]esting and release of [the] drug product do not include appropriate laboratory determination of satisfactory conformance to the final specifications,"
> (5) Because "[e]stablished laboratory control mechanisms are not followed," the "confirmed Out of Specification results are not further investigated as per the laboratory investigation SOP," and
> (6) "Laboratory controls do not include the establishment of scientifically sound and appropriate

> specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity."

(SAC ¶¶ 60-61.)

The EIR that followed the October 2017 483 Letter expanded on the observations contained in the October 2017 483 Letter and described other issues as well, including Teligent's failure to conduct appropriate investigations for OOS results in "exhibit batches" upon which the tests generating data for ANDAs are run. (SAC ¶ 62.) Oklahoma Police alleges that Teligent was submitting ANDAs without performing investigations into OOS results, and that the observations in the October 2017 483 Letter and the EIR that followed implicated GMP, GLP, and other regulations.

Teligent responded to the October 2017 483 Letter and subsequent EIR on November 6, 2017 (the last day of the Class Period) and acknowledged the accuracy of observations (2) and (5). Teligent wrote that its practice was to conclude OOS investigations once the OOS results were confirmed. That is, Teligent would report the findings of the OOS investigation to the "R&D team for further evaluation and action, but no follow up was deemed required." (SAC ¶ 70.) With respect to observation (3), Teligent acknowledged that before the October 2017 483 Letter it did not have an SOP to "ensure

that any laboratory test method being used in the laboratory ha[d] been previously validated or verified." (SAC ¶ 70.)

Finally, the FDA also inspected the Buena Facility in May 2019. Following this inspection, the FDA issued the May 2019 483 Letter, which contained the following observations:

> (1) "Drug products failing to meet established specifications are not rejected,"
> (2) "Investigations of a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product,"
> (3) "Laboratory records are deficient in that they do not include a statement of the results of tests and how they compare to the established specifications,"
> (4) "Written records are not always made of investigations into the failure of a batch or any of its components to meet specifications," and
> (5) "The written stability testing program [SOP] is not followed."

(SAC ¶ 76.)

The May 2019 483 Letter also observed that Teligent failed to follow procedures for handling complaints and annual product reviews; failed to establish control procedures to monitor manufacturing processes, causing variability in the characteristics of drug products; and failed to make records associated with drug products available for inspection. Oklahoma Police alleges that the observations in the May 2019 483 Letter implicated GMP, GLP, and other regulations.

Teligent responded to the May 2019 483 Letter and acknowledged that it needed to undertake more radical remedial efforts, including overhauling its investigation practices for OOS results. Teligent pointed to staffing issues and pledged to make additional hires in a "concerted effort to staff the organization appropriately." (SAC ¶ 81.)

3. Alleged Misrepresentations

Defendants made several statements during the Class Period regarding its ability to achieve FDA approval of its ANDAs and its ability to carry out the planned transformation of its business. Oklahoma Police alleges that these statements misled investors to believe that Teligent would be able to obtain FDA approval and achieve its stated goals, even though the results of the FDA's inspections allegedly demonstrated that Teligent would not in fact be able to meet those goals.

i. March 7, 2017 Press Release and Conference Call

On March 7, 2017, Teligent issued a press release announcing its Q4 2016 and FY 2016 results, followed by a conference call. In the press release, Grenfell-Gardner stated that Teligent was continuing "to execute and grow [its] business" and was "well underway with the significant expansion of [its] manufacturing facility" in Buena, New

Jersey. (SAC ¶ 93.) He also stated that he "believe[d] that [Teligent was] well-positioned to increase revenue up to $85 to $100 million in 2017." (SAC ¶ 93.)

In the subsequent conference call, Grenfell-Gardner pointed to Teligent's pipeline as a "unique asset" and stated that "Teligent's ability to navigate drugs through the approval process at FDA in a timely manner and launch them successfully" set the Company apart. (SAC ¶ 95.) Grenfell-Gardner contrasted Teligent with "some of the major facilities that supply the market," which "continue to have ongoing regulatory challenges" such as "warning letters . . . related to sterile injectable manufacturing sites run by some of the largest companies in the world." (SAC ¶ 101.) Grenfell-Gardner stated that Teligent was on track to finish the Buena Facility by the end of the year, which would enable the Company to meet its ANDA submission goals. In response to an analyst's question about the cadence of its ANDA submissions, Grenfell-Gardner stated that the Company was intentionally focusing more on the quality of filings, and making sure the Company could give timely and good-quality responses to the FDA's information requests, rather than the number of filings. Grenfell-Gardner also assured investors

that Teligent's investment in R&D would drive the Company's growth and profitability.

ii. March 13, 2017 Statement at the Roth Capital Conference

Grenfell-Gardner spoke at the Roth Capital Conference on March 13, 2017, where, Oklahoma Police alleges, he made materially false and misleading statements to the public. Grenfell-Gardner stated that Teligent had had a "very successful track record with the FDA," and that over the "last three audits over the past five years, there have been no 483 observations at [the Buena] site." (SAC ¶¶ 103, 107.) He assured investors that Teligent's "cooperation with the FDA has been incredibly fruitful and straightforward." (SAC ¶ 103.) He also stated that the new facility had made progress and that Teligent was "on track" to hit its goals. He touted the Company's "regulatory skills." (SAC ¶ 104.) Finally, he told investors that R&D continued to be the Company's best investment "because the FDA is approving the drugs that [Teligent] submit[s]." (SAC ¶ 106.)

iii. The 2016 Form 10-K and 2017 10-Qs

On March 15, 2017, Teligent filed its Form 10-K for 2016 ("2016 10-K"). In the 2016 10-K, Teligent noted that it must "comply with cGMPs," that its facilities and procedures were "subject to periodic inspection by the FDA," and that "[a]ny

material deviations from pharmaceutical cGMPs or other applicable requirements identified during such inspections may result in recalls or other enforcement actions, including warning letters . . . .” (SAC ¶ 108.) The 2016 10-K also disclosed that Teligent had “an FDA-registered, cGMP-compliant facility that is equipped for manufacturing topical, semi-solid and liquid products.” (SAC ¶ 110.) On May 10 and August 9, 2017, Teligent filed its Form 10-Qs for the first and second quarters of 2017 (“2017 10-Qs”), which incorporated by reference the risk disclosures of the 2016 10-K.

iv. May 2, 2017 Press Release and Conference Call

Teligent issued a press release on May 2, 2017, presenting the Company’s Q1 2017 quarterly results and stating that two of the Company’s ANDAs had received approval. In a subsequent conference call, Grenfell-Gardner stated that the Company was “committed to upholding [its] responsibilities with respect to the FDA to ensure the timely processing of [its] applications,” and that the business was “[b]uilt on a solid product development platform, excellent regulatory capabilities and timely and effective product launch.” (SAC ¶¶ 113-14.) In response to a question, Grenfell-Gardner indicated that Teligent was “ready to produce

injectable products by the end of [2017],” and expressed excitement about the Company’s “internally developed pipeline.” (SAC ¶¶ 115-16.)

v. May 3, 2017 Deutsche Bank Health Care Conference

At the Deutsche Bank Health Care Conference on May 3, 2017, Grenfell-Gardner made the following statement: “If you look at the [Buena] manufacturing site, so this is the site that’s under significant expansion at the moment. It had a very solid track record with [the] FDA -- the audits conducted over the last five years, there’ve been no 483 observations related to the site.” (SAC ¶ 118.)

vi. May 16, 2017 Bank of America Merrill Lynch Healthcare Conference

At the Bank of America Merrill Lynch Healthcare Conference on May 16, 2017, Grenfell-Gardner made the following statement regarding Teligent’s pipeline of ANDA submissions: “All of this we do pretty much internally through a facility that we have in New Jersey, it’s an FDA approved site[.] No 483 observations in the last three inspection cycles, and it’s a site that we’re extending pretty rapidly in order to meet the demands of both . . . the pipeline as well as the strategy that we’ve set out.” (SAC ¶ 120.)

Grenfell-Gardner again touted the strength of Teligent’s pipeline and predicted that Teligent “should be in a position

to file somewhere around my goal of 20 ANDAs a year in injectables." (SAC ¶ 122.) He contrasted Teligent's regulatory compliance with other similar companies, praising the Company's responsiveness to the FDA. And, in a PowerPoint presentation accompanying his speech, Grenfell-Gardner pointed to the Company's "[t]rack record of successful FDA audits," with "[t]hree audits conducted over the past 5 years (last audit in January 2016) with no 483 observations." (SAC ¶ 124.) Separately, the PowerPoint stated that Teligent's facility has "[n]o 483 observations in the last three cGMP inspections" and that its facility was "cGMP-compliant." (SAC ¶ 124.)

vii. August 8, 2017 Press Release and Conference Call

Teligent issued a press release on August 8, 2017 announcing its quarterly results for Q2 2017. Later that day, Grenfell-Gardner disclosed on a conference call that several pending ANDAs had been "impacted by regulatory inspections at 3 of [Teligent's] API [active pharmaceutical ingredient] suppliers," and that these suppliers had received 483 observations. (SAC ¶ 128.) He assured investors that he "believe[d] that there [were] approximately 10 potential approvals that [Teligent] could anticipate before the end of

the year." (SAC ¶ 129.) He also, again, lauded the robustness of Teligent's R&D pipeline.

4. Teligent Announces Q3 2017 Results

Oklahoma Police alleges that the truth about Teligent's pipeline and regulatory woes emerged on November 6, 2017, when the Company issued a corrective disclosure in the form of a press release and subsequent conference call announcing its results for Q3 2017. The press release disclosed a net loss of $8.9 million for the quarter, compared to $2.7 million in net loss in the same quarter a year earlier. It also reported a 15 percent decrease in revenue as compared to the same quarter a year earlier, and reduced its FY2017 revenue guidance. Grenfell-Gardner was quoted in the release as stating that the Company's "results and [its] revised outlook for the remainder of the year[] are a result of the knock-on effect of ANDA approval delays" and the decreased performance of one product. (SAC ¶ 135.)

In a conference call the same day, Grenfell-Gardner attributed the reduction in the FY2017 revenue guidance "almost entirely" to "pipeline delays." (SAC ¶ 136.) He noted that the Company had products that it believed were "ripe for approval, . . . but then you'd come up with another sort of question and another cycle of review." (SAC ¶ 136.) He

disclosed that Teligent had "faced manufacturing challenges," including an apparent reference to the contaminated product reported by the FDA in the October 2017 483 Letter. (SAC ¶ 139.) He also pointed to issues at Teligent's suppliers' manufacturing sites, noting that delays relating to four of the ten ANDA submissions that Teligent hoped to get approved by the end of the year involved "minor complete response letters that really were often related to the [supplier's] sites that we talked about earlier or other sort of minor issues." (SAC ¶ 137.) More generally, in the conference call Grenfell-Gardner provided updates on the Company's manufacturing facility, pushing back the timeline on when the facility would be validated and when it would start production.

On the next trading day, November 7, 2017, the price of Teligent common stock dropped 43.62 percent. Oklahoma Police alleges that it and similarly situated members of the proposed class purchased Teligent common stock at artificially inflated prices caused by the Defendants' misconduct, and that when the manufacturing issues were disclosed, the price dropped, causing their losses. Oklahoma Police alleges that they were unaware of the three 483 Letters, the issues described in those letters, and the delays in the development

of the new facility. Oklahoma Police further alleges that Defendants' misrepresentations and omissions concealed the adverse material facts from the market, leading investors to believe (wrongly, according to Oklahoma Police) that Teligent was complying with FDA regulations, producing a pipeline of ANDA submissions, and nearing the ability to produce injectable drugs.

B. PROCEDURAL BACKGROUND

Plaintiffs filed a complaint on April 15, 2019 (see Dkt. No. 1) and, following selection of lead counsel, the Amended Complaint on September 13, 2019. Consistent with the Court's Individual Practices, counsel for Defendants wrote to Oklahoma Police regarding an anticipated motion to dismiss the Amended Complaint. (See October 25 Letter.) Oklahoma Police responded to the October 25 Letter (see November 5 Letter), and pursuant to a jointly stipulated scheduling order (see Dkt. No. 38), Oklahoma Police filed the SAC on December 9, 2019.

On January 15, 2020, Defendants wrote to Oklahoma Police regarding an anticipated motion to dismiss the SAC. (See Motion.) Defendants make six arguments. First, they argue that the alleged omissions were not actionable and that they were not required to disclose the 483 letters. Second,

Defendants contend that their statements regarding cooperation with the FDA were either accurate or otherwise non-actionable puffery or statements of opinion. Third, Defendants state that Oklahoma Police misread the 483 letters, and that neither the September 2016 nor the October 2017 483 Letter concerned widespread or systemic issues at Teligent, and that in particular, the October 2017 483 Letter cannot render previous challenged statements misleading because it was issued after all of the challenged statements. Fourth, Defendants assert that their statements about Teligent's prospects for growth and future performance are protected by the Private Securities Litigation Reform Act's ("PSLRA's") safe harbor for forward-looking statements. Fifth, Defendants argue that the SAC fails to plead scienter because it relies exclusively on Grenfell-Gardner's position as CEO to establish his knowledge of the alleged issues at Teligent. Lastly, Defendants argue that the SAC fails to plead loss causation, because the purported "corrective disclosure" in November 2017 neither corrected any prior misstatement or revealed any concealed information, but rather reflected Teligent's revised outlook, and as the SAC acknowledges, Defendants have still not disclosed any of the three 483 Letters.

By letter dated January 22, 2020, Oklahoma Police responded to the Motion. (See Opposition.) Oklahoma Police point to the SAC's allegations that Grenfell-Gardner repeatedly stated throughout the Class Period that Teligent had received "no 483 observations" from the FDA, when that was not in fact true. (Opposition at 1.) Oklahoma Police argues that Defendants had an obligation to disclose the 483 letters and, furthermore, that by not addressing these allegations in its Motion, Defendants have conceded that Grenfell-Gardner's statements were false and misleading. With respect to scienter, Oklahoma Police points to the allegations in the SAC regarding Grenfell-Gardner's knowledge of the concealed information. Oklahoma Police lastly contends that the SAC adequately pleads loss causation based on Teligent's corrective disclosures and the materialization of concealed risks.

By letter dated January 28, 2020, Defendants alerted the Court that the pre-motion letter exchange had not resolved the parties' differences and urged the Court to dismiss the SAC. (See Reply.) Defendants first address Grenfell-Gardner's alleged statements that Teligent had received "no 483 observations" when it had in fact received a 483 letter just before the Class Period, in September 2016. This allegation,

according to Defendants, takes Grenfell-Gardner's statements out of context. According to Defendants, Grenfell-Gardner was referring to cGMP auditing, while the September 2016 letter was issued in connection with the Bioresearch Monitoring ("BIMO") program. Defendants contend that the audience to which Grenfell-Gardner was speaking would have understood this distinction. Defendants also argue that they had no obligation to disclose their communications with the FDA, and that the SAC does not adequately plead loss causation because Defendants properly disclosed potential delays in testing, submitting, and commercializing new products, and the November 6, 2017 disclosures did not bring to light any information that was improperly concealed.

Having considered the parties' briefing, the facts as set forth in the SAC, and the relevant case law, the Court will deny in part Defendants' Letter Motion to dismiss the SAC pursuant to Rule 12(b)(6).

II. LEGAL STANDARD

A. RULE 12(B)(6) MOTION TO DISMISS

Rule 12(b)(6) provides for dismissal of a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as

true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). This standard is met "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. A complaint should be dismissed if the plaintiff has not offered factual allegations sufficient to render the claims facially plausible. See id. However, a court should not dismiss a complaint for failure to state a claim if the factual allegations sufficiently "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

In resolving a Rule 12(b)(6) motion, the Court's task is "merely to assess the legal feasibility of the complaint, not to assay the weight of the evidence which might be offered in support thereof." In re Initial Pub. Offering Sec. Litig., 383 F. Supp. 2d 566, 574 (S.D.N.Y. 2005) (internal quotation marks omitted), aff'd sub nom. Tenney v. Credit Suisse First Boston Corp., No. 05 Civ. 3430, 2006 WL 1423785 (2d Cir. May 19, 2006); accord In re MF Glob. Holdings Ltd. Sec. Litig., 982 F. Supp. 2d 277, 302 (S.D.N.Y. 2013). In this context, the Court must draw reasonable inferences in favor of the non-moving party. See Chambers v. Time Warner, Inc., 282 F.3d

147, 152 (2d Cir. 2002). However, the requirement that a court accept the factual allegations in the claim as true does not extend to legal conclusions. See Iqbal, 556 U.S. at 678.

In adjudicating a Rule 12(b)(6) motion, a court must confine its consideration "to facts stated on the face of the complaint, in documents appended to the complaint or incorporated in the complaint by reference, and to matters of which judicial notice may be taken." Leonard F. v. Israel Disc. Bank of N.Y., 199 F.3d 99, 107 (2d Cir. 1999) (internal quotation marks omitted). However, plaintiffs claiming fraud -- including securities fraud concerning material misstatements and omissions -- must satisfy the heightened pleading requirements of Federal Rule of Civil Procedure 9(b) ("Rule 9(b)") by "stat[ing] with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). "Allegations that are conclusory or unsupported by factual assertions are insufficient." ATSI Commc'ns, Inc. v. Shaar Fund, Ltd., 493 F.3d 87, 99 (2d Cir. 2007).

The PSLRA also imposes heightened pleading standards for plaintiffs alleging securities fraud. When a plaintiff alleges that defendants made misleading statements or omissions, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why

the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). Plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." Rombach v. Chang, 355 F.3d 164, 174 (2d Cir. 2004). To adequately plead scienter, "the complaint shall . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). A court shall grant a motion to dismiss a securities fraud complaint if these requirements are not met.

B. THE EXCHANGE ACT

To state a claim for misrepresentation or omission under Section 10(b) and Rule 10b-5, "a plaintiff must allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury." ATSI, 493 F.3d at 105; see also Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148,

157 (2008). Here, only the first, second, and fifth elements are at issue.

Separately, "Section 20(a) of the Exchange Act imposes derivative liability on parties controlling persons who commit Exchange Act violations." In re Vivendi, S.A. Sec. Litig., 838 F.3d 223, 238 n.6 (2d Cir. 2016). "To establish a prima facie case" for Section 20(a) liability, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." ATSI Commc'ns, 493 F.3d at 108.

1. Misstatements or Omissions of Material Fact

With respect to the first element of a claim brought under Section 10(b) and Rule 10b-5, the PSLRA requires that a complaint "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1); see also Rombach, 355 F.3d at 172 ("To meet the pleading standard of Rule 9(b), this Court has repeatedly required, among other things, that

the pleading explain why the statements were fraudulent."). A "pure omission" is actionable "only when the [defendant] is subject to a duty to disclose the omitted facts." Vivendi, 838 F.3d at 239. Although "Rule 10b-5 imposes no duty to disclose all material, nonpublic information, once a party chooses to speak, it has a 'duty to be both accurate and complete.'" Plumbers' Union Local No. 12 Pension Fund v. Swiss Reinsurance Co., 753 F. Supp. 2d 166, 180 (S.D.N.Y. 2010) (quoting Caiola v. Citibank, N.A., N.Y., 295 F.3d 312, 331 (2d Cir. 2002)). "Disclosure is required . . . only when necessary 'to make statements made, in the light of the circumstances under which they were made, not misleading.'" Kleinman v. Elan Corp., 706 F.3d 145, 153 (2d Cir. 2013) (quoting Matrixx Initiatives, Inc. v. Siracusano, 563 U.S. 27, 44 (2011)).

For omitted facts to be material, "there must be a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." Basic Inc. v. Levinson, 485 U.S. 224, 231–32 (1988) (quoting TSC Indus., Inc. v. Northway, Inc., 426 U.S. 438, 449 (1976)). "[W]hether an alleged misrepresentation or omission is material necessarily depends

on all relevant circumstances of the particular case." Ganino v. Citizens Utils. Co., 228 F.3d 154, 162 (2d Cir. 2000). Because materiality is a mixed question of law and fact, "a complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." Id.

The PSLRA contains a safe harbor provision that applies to forward-looking statements, such as "a statement of future economic performance, including any such statement contained in a discussion and analysis of financial condition by the management." Slayton v. Am. Express Co., 604 F.3d 758, 767 (2d Cir. 2010) (quoting 15 U.S.C. § 78u-5(i)(1)(C)). Under the PSLRA, a person "shall not be liable with respect to any forward-looking statement," 15 U.S.C. § 77z-2(c), but only to the extent that it (1) is accompanied by meaningful cautionary language; (2) is immaterial; or (3) the plaintiff failed to prove the statement was made with actual knowledge that it was false or misleading. See Slayton, 604 F.3d at 766.

When evaluating the adequacy of cautionary language, a court must "identify the allegedly undisclosed risk and then read the allegedly fraudulent materials -- including the

cautionary language -- to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist." In re Focus Media Holding Ltd. Litig., 701 F. Supp. 2d 534, 540 (S.D.N.Y. 2010) (internal quotation marks omitted). "Cautionary words about future risk cannot insulate from liability the failure to disclose that the risk has transpired." Rombach, 355 F.3d at 173; see also In re Prudential Sec. Inc. P'ships Litig., 930 F. Supp. 68, 72 (S.D.N.Y. 1996) ("To warn that the untoward may occur when the event is contingent is prudent; to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit.").

Certain types of statements, including puffery and opinion statements, are not actionable because they are not materially misleading. "Puffery is an optimistic statement that is so vague, broad, and non-specific that a reasonable investor would not rely on it, thereby rendering it immaterial as a matter of law." In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d 367, 384 (S.D.N.Y. 2012); see also Vivendi, 838 F.3d at 245 ("Puffery encompasses statements that are too general to cause a reasonable investor to rely upon them, and thus cannot have misled a reasonable investor." (internal

citations and alteration omitted)). This rule permits companies "to operate with a hopeful outlook," because corporate officers "are not required to take a gloomy, fearful or defeatist view of the future." Rombach, 355 F.3d at 174. But statements are not puffery when they constitute "misrepresentations of existing facts" that were made even though the speaker "knew that the contrary was true." Novak v. Kasaks, 216 F.3d 300, 315 (2d Cir. 2000) (rejecting a puffery argument where "the defendants stated that the inventory situation was 'in good shape' or 'under control' while they allegedly knew that the contrary was true"); see also In re Bank of Am. Corp. Sec., Derivative & ERISA Litig., 757 F. Supp. 2d 260, 310 (S.D.N.Y. 2010) ("[T]here is a difference between enthusiastic statements amounting to general puffery and opinion-based statements that are anchored in 'misrepresentations of existing facts.'" (quoting Novak, 216 F.3d at 315)).

2. Scienter

With respect to the second element of a claim brought under Section 10(b) and Rule 10b-5, scienter is "a mental state embracing intent to deceive, manipulate, or defraud." Tellabs, Inc. v. Makor Issues & Rights, Ltd., 551 U.S. 308, 319 (2007). Under Rule 9(b) and the PSLRA, a plaintiff must

"state with particularity the facts giving rise to a strong inference that the defendant acted with the required state of mind." Rombach, 355 F.3d at 176 (alteration omitted). A complaint will survive a motion to dismiss only if "the inference of scienter [is] cogent and at least as compelling as any opposing inference one could draw from the facts alleged." Slayton, 604 F.3d at 766. When assessing whether a strong inference exists, "the allegations are not to be reviewed independently or in isolation, but the facts alleged must be 'taken collectively.'" Id. (quoting Tellabs, 551 U.S. at 323).

Oklahoma Police can satisfy this scienter requirement by alleging facts that either "(1) show[] that the defendants had both motive and opportunity to commit the fraud or (2) constitut[e] strong circumstantial evidence of conscious misbehavior or recklessness." ATSI Commc'ns, 493 F.3d at 99. "The opportunity to commit fraud is generally assumed where the defendant is a corporation or corporate officer." Dodona I, LLC v. Goldman, Sachs & Co., 847 F. Supp. 2d 624, 638 (S.D.N.Y. 2012). Motive, however, requires Oklahoma Police to allege facts showing "concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged." Kalnit v. Eichler, 264 F.3d 131, 139

(2d Cir. 2001). Merely alleging "goals that are possessed by virtually all corporate insiders, such as the desire to . . . sustain the appearance of corporate profitability . . . or the desire to maintain a high stock price in order to increase executive compensation" will not suffice. See S. Cherry St., LLC v. Hennessee Grp. LLC, 573 F.3d 98, 109 (2d Cir. 2009).

If a complaint pleads recklessness or conscious misbehavior rather than opportunity and motive, "the strength of the circumstantial allegations must be correspondingly greater." Kalnit, 264 F.3d at 142. To sufficiently plead recklessness, the complaint must allege conduct which is "highly unreasonable and which represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." Id. In this regard, "a complaint sufficiently pleads scienter where it alleges defendants had knowledge of facts or access to information contradicting their public statements." Sharette v. Credit Suisse Int'l, 127 F. Supp. 3d 60, 80 (S.D.N.Y. 2015).

3. Loss Causation

Finally, a plaintiff is required to prove both transaction causation, also known as reliance, and loss

causation. Lentell v. Merrill Lynch & Co., 396 F.3d 161, 172 (2d Cir. 2005); see also 15 U.S.C. § 78u–4(b)(4). Transaction causation, which is not disputed here, only requires allegations that "but for the claimed misrepresentations or omissions, the plaintiff would not have entered into the detrimental securities transaction." ATSI Commc'ns, 493 F.3d at 106 (quoting Lentell, 396 F.3d at 172). Loss causation, which is in dispute, is the proximate causal link between the alleged misconduct and the plaintiff's economic harm. See Dura Pharm., Inc. v. Broudo, 544 U.S. 336, 346 (2005); Lentell, 396 F.3d at 172. To that end, the plaintiff's complaint must plead that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement.

III. DISCUSSION

The Court addresses each of Defendants' arguments in turn, starting with whether the alleged misstatements and omissions are material and pleaded with sufficient particularity, as well as whether they are protected by the PSLRA's safe harbor; the Court finds that while certain of the challenged statements are not actionable, certain others have been adequately pled. The Court then addresses the issues of scienter and loss causation, and holds that Oklahoma Police

has sufficiently alleged both. Lastly, the Court addresses the sufficiency of Oklahoma Police's claim arising under Section 20(a) of the Exchange Act.

A. ALLEGED MISSTATEMENTS AND OMISSIONS

As described above, Oklahoma Police is challenging statements made between March 7, 2017 and August 8, 2017. The Court holds that some are non-actionable, but will nevertheless grant the Motion only in part because Oklahoma Police has stated a claim based on other statements made by Defendants. The Court discusses the challenged statements below, first explaining why four sets of statements are non-actionable before turning to the remaining actionable statements.

1. Non-Actionable Statements

Turning first to the non-actionable statements, the Court is persuaded by Defendants' argument that certain statements made in the 2016 10-K and 2017 10-Qs are not actionable. In addition, the Court finds that a majority of the statements made in the May 2, 2017 press release and conference call, the March 7, 2017 press release, and the August 8, 2017 conference call constitute puffery, are protected by the PSLRA safe harbor, or are otherwise non-actionable.

First, the 2016 10-K contained a section titled "Risk Disclosures," which was incorporated into the 2017 10-Qs and described Teligent's obligations to "comply with cGMPs" and submit to "periodic inspection by the FDA." (SAC ¶ 108.) While Oklahoma Police alleges that these reports are misleading because Teligent was not, in fact, complying with cGMP, the Court finds that the statements are merely statements of fact. Teligent was not commenting on its compliance or lack of compliance, but rather disclosing the risks it (and any other drug company) faced in the event of non-compliance. While it would have been "deceit[ful]" to warn that it was merely "possible for the unfavorable events to happen when they have already occurred," the language in the 2016 10-K and 2017 10-Qs is factually accurate. In re Prudential Sec. Inc. P'ships Litig., 930 F. Supp. at 72. The September 2016 483 Letter did not affect Teligent's obligations. Because the statements were true representations of the requirements placed on Teligent, the Court finds these risk disclosure statements not misleading and thus not actionable.

The statements made in the May 2, 2017 press release and conference call are also non-actionable. Grenfell-Gardner's statement that Teligent was committed to its FDA responsibilities was not a misrepresentation of existing

facts, but rather an assertion as vague and non-specific as it was optimistic. See In re Gen. Elec. Co. Sec. Litig., 857 F. Supp. 2d at 384. As such, it constitutes puffery, and is non-actionable, as are Defendants' statements regarding their cooperation with the FDA. See In re EDAP TMS S.A. Sec. Litig., No. 14 Civ. 6069, 2015 WL 5326166, at *9–10 (S.D.N.Y. Sept. 14, 2015) (statements indicating "that the [FDA approval] process was 'on track' and making continued 'progress,'" or "declar[ing defendants'] belief that they were 'moving through the approval process in a timely manner,'" "constitute inactionable puffery"). To be sure, there is a difference between puffery and "opinion-based statements that are anchored in 'misrepresentations of existing facts.'" In re Bank of Am. Corp. Sec., Derivative & ERISA Litig., 757 F. Supp. 2d at 310 (quoting Novak, 216 F.3d at 315). Here, any daylight between Grenfell-Gardner's statement and what eventually transpired does not amount to a misrepresentation of fact, but rather optimism that, in retrospect, was misguided. See In re Aratana Therapeutics Inc. Sec. Litig., 315 F. Supp. 3d 737, 757 (S.D.N.Y. 2018) (assertions of a company's "remarkable progress" in "advancing [its] expanding pipeline toward commercialization" constituted puffery). Similarly, Grenfell-Gardner's projection that Teligent would

be "ready to produce injectable products by the end of [2017]" is non-actionable. (SAC ¶ 115.) Oklahoma Police argues that the statement was false because Teligent was not, in fact, on track to meet its timeline to produce injectable products, because the facility was already experiencing significant delays. But Oklahoma Police cannot demonstrate actual knowledge that the facility would not be ready. The fact that Teligent had received the September 2016 483 Letter does not change this conclusion, as a review of the issues described therein suggests the violations were correctable, at least with sufficient dedicated resources and time. See In re Discovery Labs. Sec. Litig., No. 06-1820, 2007 WL 789432, at *4 (E.D. Pa. Mar. 15, 2007) (holding that a 483 letter that observed violations such as "failure properly to control conditions, failure to investigate variations from those controls, and failure to keep proper documentation" raised issues that, while potentially "expensive or time-consuming to remedy, [were] eminently correctable"). Because Oklahoma Police does not allege with particularity that Grenfell-Gardner had actual knowledge that the facility could not be ready on time, this statement is non-actionable.

Similarly, the Court also finds that Oklahoma Police has not stated a claim with respect to statements made in

Teligent's March 7, 2017 press release. The March 7, 2017 press release quotes Grenfell-Gardner as stating that Teligent was continuing to grow its business and was "well underway" with the expansion of its Buena facility, and stated his belief that Teligent was "well-positioned to increase revenue up to $85 to $100 million in 2017." (SAC ¶ 93.) Such statements are either classic puffery or protected by the safe harbor for the reasons described above.

While it is a closer call, the Court finds that Oklahoma Police has not stated a claim with respect to statements made in the conference call following the August 8, 2017 press release. On this call, Grenfell-Gardner disclosed that three of Teligent's API suppliers had received 483 observations, which had caused delays in the FDA's approval of several pending ANDAs.[5] Theoretically, this statement could be seen to imply that Teligent, unlike certain of its suppliers and certain other manufacturers, had no comparable regulatory challenges. Indeed, that is Oklahoma Police's position. But

[5] Other statements made during the August 8, 2017 conference call are non-actionable opinion statements, such as Grenfell-Gardner's statement that he "believe[d] that there are approximately 10 potential approvals that [Teligent] could anticipate before the end of the year." (SAC ¶ 129.) Such statements are non-actionable if "the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." In re Aratana Therapeutics Inc. Sec. Litig., 315 F. Supp. 3d at 758. While Oklahoma Police alleges that Defendants had "no basis" (SAC ¶ 131) to believe that, they do not allege actual knowledge with particularity, even considering the September 2016 483 Letter. In re Discovery Labs. Sec. Litig., 2007 WL 789432, at *4.

it is too far of a stretch to hold that these statements contained material omissions. The Court does not consider Grenfell-Gardner's statement that certain of Teligent's suppliers had received "483 observations" to be materially misleading. While he noted the impact of the suppliers' regulatory inspections on Teligent's operations, he did not compare the relative strength of Teligent's regulatory compliance with that of the suppliers.

2. Actionable Statements

In contrast, the Court finds that Oklahoma Police has stated a claim with respect to portions of the 2016 10-K, the March 7, 2017 conference call, and the statements made at the March 13, 2017 Roth Capital Conference, the May 3, 2017 Deutsche Bank Health Care Conference, and the May 16, 2017 Bank of America Merrill Lynch Healthcare Conference.

In its 2016 10-K and 2017 10-Qs, Teligent noted that deviations from cGMPs or other requirements may result in FDA enforcement actions such as "warning letters." The Court finds that Oklahoma Police has adequately alleged that the specific mention of the possibility of receiving a warning letter, while omitting any reference to the September 2016 483 Letter, was materially misleading under the circumstances.

Warning letters from the FDA are generally public and convey the FDA's "find[ing] that a manufacturer has significantly violated FDA regulations"[6]; as such, they differ in key respects from 483 Letters.[7] See Plumbers & Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc., 679 F.3d 952, 955 (7th Cir. 2012) ("In industry jargon, a '483' is an observation by an inspector, providing information about significant objectionable conditions (not serious enough to merit a warning or any formal action by the agency) . . . ."). Nevertheless, this Court recently noted in a different case that while a 483 letter "is technically not the same" as a warning letter, when viewed "under the totality of the circumstances," it might be akin to a warning letter if its contents were "serious enough that a reasonable investor would consider it a substantially equivalent FDA warning." Schaeffer v. Nabriva Therapeutics PLC, No. 19 Civ. 4183, 2020 U.S. Dist. LEXIS 78035, at *34-35 (S.D.N.Y. Apr. 28, 2020).

Here, although the number of observations in the September 2016 483 Letter is relatively small (five, half the

[6] FDA, About Warning and Close-Out Letters, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/about-warning-and-close-out-letters.

[7] The Court takes judicial notice of the fact that a search of the FDA's database of warning letters reveals only one directed at Teligent, dated November 26, 2019. See Fed. R. Evid. 201.

number of observations in Schaeffer), the seriousness of those observations counsels in favor of holding that a reasonable investor could consider the letter akin to a warning letter. Indeed, the FDA told Teligent in its February 21, 2017 Letter -- less than a month before Teligent filed the 2016 10-K -- that it had "concerns about the validity and integrity of the studies conducted at [the Company's] study site." (SAC ¶ 56.) Based on the allegations in the SAC, and considering the totality of the circumstances, the Court finds that the 2016 10-K could plausibly have misled a reasonable investor as to the status of Teligent's interactions with the FDA at that point.

For substantially the same reasons, the Court finds that Oklahoma Police has stated a claim with respect to statements made during the conference call that followed the March 7, 2017 press release. On this call, Grenfell-Gardner contrasted Teligent with other "major facilities that supply the market" and that "continue to have ongoing regulatory challenges," such as "warning letters." (SAC ¶ 101.) As noted above, although warning letters differ in key respects from 483 letters, the Court finds that Grenfell-Gardner's comparison of Teligent to manufacturers who had received warning letters

(or, more generally, had "ongoing regulatory challenges") could plausibly have misled a reasonable investor.[8]

The 2016 10-K separately disclosed that Teligent had a "cGMP-compliant facility that is equipped for manufacturing topical, semi-solid and liquid products." (SAC ¶ 110.) Oklahoma Police alleges that this statement is misleading because Teligent's facility was not, in fact, cGMP-compliant, as demonstrated by the observations of the 483 Letters and CW 1. To be sure, the issuance of a 483 Letter is not a definitive finding by the FDA that a facility is non-cGMP-compliant. City of Pontiac Gen. Emps.' Ret. Sys. v. Stryker Corp., 865 F. Supp. 2d 811, 825 (W.D. Mich. 2012). In fact, as discussed above, it is not even necessarily akin to a warning letter. Instead, as the Eighth Circuit has held, "[t]he issuance of a Form 483 represents a *risk* that the FDA may take corrective action against a company." Pub. Pension Fund Grp. v. KV Pharm. Co., 679 F.3d 972, 982-83 (8th Cir. 2012) (emphasis added).

[8] The March 7, 2017 conference call also contained various other statements regarding Teligent's growth, its pipeline, its "ability to navigate drugs through the approval process at FDA in a timely manner," and its timeline for producing injectable products. (SAC ¶ 95.) For the reasons discussed above with respect to May 2, 2017 press release and conference call, the Court finds these to be puffery or otherwise non-actionable. See In re Discovery Labs. Sec. Litig., 2007 WL 789432, at *4; In re Aratana Therapeutics Inc. Sec. Litig., 315 F. Supp. 3d at 758.

Defendants point out that the FDA did not take such action.[9] (Motion at 2.)

Nevertheless, based on the type of observations in the September 2016 483 Letter, the Court is persuaded that the claim that the facility was cGMP compliant was misleading. Oklahoma Police has sufficiently alleged that the five observations in the September 2016 483 Letter "implicate[d] the GMP, GLP, and other pertinent regulations." (SAC ¶ 52.) For example, Oklahoma Police points out that the "Lab Controls and Production and Process Controls sections of the GMP, GLP, and other regulations[] prohibit Teligent's failure to store reserve samples and have SOPs for such storage" (i.e., the first observation and the EIR comments), while "the Lab Controls and Production and Process Controls sections of the GMP prohibit Teligent's use of unrepresentative samples in its studies" (i.e., the third and fourth observations). (SAC ¶ 52.)

While the September 2016 483 Letter contained five observations, which may seem like a small number in absolute

[9] Oklahoma Police also relies on CW 1's observations to show noncompliance, but does not allege with particularity that CW 1's observations may substitute for a finding by the FDA that the facility was non-compliant, or that Defendants were aware of CW 1's observations. CW 1, while under pressure to close investigations early and take other actions with which she or he felt uncomfortable, may not have expressed those feelings to Grenfell-Gardner or any other employee; Oklahoma Police does not allege otherwise beyond stating that CW 1 recalled that at some point (possibly January 2018) he or she requested and was denied additional resources.

terms, Oklahoma Police has sufficiently pled with particularity that the letter and subsequent EIR raised concerns regarding the facility's compliance with cGMP. Indeed, following the EIR, the FDA indicated in the February 21, 2017 Letter that it had "concerns about the validity and integrity of the studies conducted at your study cite."[10] (SAC ¶ 56.) As the Court noted in Schaeffer, "failing to disclose a recent Form 483 that lists numerous cGMP violations could render misleading a company's statements that it is presently substantially in compliance with cGMP regulations." Schaeffer, 2020 U.S. Dist. LEXIS 78035, at *33. Accordingly, because Oklahoma Police has pled that the September 2016 483 Letter raised concerns about the facility's compliance with cGMP, it has pled with particularity that the claim that the facility was cGMP compliant was misleading.

The Court also holds that Oklahoma Police has stated a claim with respect to Grenfell-Gardner's statements at three separate healthcare conferences. At the March 13, 2017 Roth Capital Conference, Grenfell-Gardner stated that Teligent had a "very successful track record with the FDA" and that in the

[10] Defendants point out that the February 21, 2017 Letter demonstrates the FDA's view that "[Teligent's] proposed corrective and preventative actions appear adequate." (Reply at 3.) But even the portion quoted by Defendants contains a caveat -- the corrective actions would be adequate "*if* they are implemented and executed properly." (Id. (emphasis added).) The quoted language therefore does not alter the Court's conclusion.

"last three audits over the past five years, there have been no 483 observations at [the Buena] site." (SAC ¶¶ 103, 107.) Similarly, at the May 3, 2017 Deutsche Bank Health Care Conference, Grenfell-Gardner stated that the Buena site "had a very solid track record with [the] FDA -- the audits conducted over the last five years, there've been no 483 observations related to that site." (SAC ¶ 118.) And again at the May 16, 2017 Bank of America Merrill Lynch Healthcare Conference, Grenfell-Gardner stated that Buena had had "[n]o 483 observations in the last three inspection cycles." (SAC ¶ 120.)[11]

The Court finds that these statements contain "omissions of material fact." ATSI Commc'ns, 493 F.3d at 105. To a "reasonable investor," there was a "substantial likelihood that the disclosure of the omitted fact" -- here, the existence of the September 2016 483 Letter -- "would have been viewed . . . as having significantly altered the 'total mix' of information made available." Basic Inc., 485 U.S. at

[11] As an initial matter, Oklahoma Police notes that Defendants' Motion failed to address the SAC's numerous allegations that Grenfell-Gardner made false and misleading statements that Teligent had "no 483 observations," and argues that Defendants have "thereby conceded that these statements are false and misleading." (Opposition at 1-2.) Defendants do not specifically respond to this point, although, as discussed below, they do counter Oklahoma Police's arguments more generally in the Reply. Nevertheless, the Court need not decide whether Defendants have conceded the issue because even considering the arguments in Defendants' Reply, the Court would deny the Motion.

231-32 (quoting TSC Indus., Inc., 426 U.S. at 449). As the Second Circuit has noted, "a complaint may not properly be dismissed . . . on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." Ganino, 228 F.3d at 162. The existence of the September 483 Letter is not so "obviously unimportant" that reasonable minds could not differ on the question of its importance.

Defendants' primary response to Oklahoma Police's allegations is that they were under no legal "obligat[ion] to disclose the 483 letters or otherwise comment on their interactions with the FDA." (Motion at 1.) In other words, Defendants' position is that they were under no *general* legal obligation to disclose the 483 letters. The law does not provide strong support for that position.

The Court recently had occasion to consider the same argument in Schaeffer, and as the Court noted there, the case law is not well developed on the materiality of 483 letters, particularly within the Second Circuit. For example, one district court has held that a 483 letter was per se material because it contained "facts bearing on possible delays in FDA approval," Yanek v. Staar Surgical Co., 388 F. Supp. 2d 1110,

1129-30 (C.D. Cal. 2005), while another has held that a 483 letter was per se immaterial because, as discussed above, such letters are "not the final word on whether . . . [a] facility was in compliance with FDA regulations." City of Pontiac Gen. Emps.' Ret. Sys., 865 F. Supp. 2d at 825.

Among the Courts of Appeal, only the Eighth Circuit has provided clear guidance, holding that "the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading . . . depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." KV Pharm. Co., 679 F.3d at 982-83. As the Court noted in Schaeffer, "[t]he large number of decisions denying motions to dismiss Section 10(b) claims involving Forms 483 bolsters the conclusion that Forms 483 may be material depending on the circumstances alleged." Schaeffer, 2020 U.S. Dist. LEXIS 78035, at *25 (collecting cases). The Court held that a failure to disclose a 483 letter was "actionable only if disclosure was necessary to render the statements" at issue not misleading. Id. at *27. For example, and as discussed above with respect to the 2016 10-K, "failing to disclose a recent Form 483 that lists

numerous potential cGMP violations could render misleading a company's statements that it is presently substantially in compliance with cGMP regulations." Schaeffer, 2020 U.S. Dist. LEXIS 78035, at *33.[12]

In arguing that they were under no general legal obligation to disclose the September 2016 483 Letter, Defendants rely on Acito v. IMCERA Grp., 47 F.3d 47, 53 (2d Cir. 1995), which held that the failure to disclose certain deficiencies noted in two FDA inspections was not material. Defendants cite to Acito for the more general proposition that they were not obligated to disclose the negative results of an FDA inspection. See also, e.g., In re Sanofi Sec. Litig., 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) (collecting cases in which interim FDA feedback other than 483 letters considered not material).

The Court finds that Acito is distinguishable. There, the plant at issue was one of thirty of the defendant's business locations and produced one percent of its products, the FDA took no materially adverse action, and the number of deficiencies was reduced in the second of the two inspections, suggesting improvement. In contrast, the allegations of the

[12] The Court denied the motion to dismiss on the ground that plaintiffs had failed to plead scienter. Schaeffer, 2020 U.S. Dist. LEXIS 78035, at *44-45.

SAC center on Teligent's one manufacturing facility.[13] Cf. Acito, 47 F.3d at 52-53 (noting the burden that would be presented by requiring the public dissemination of "the results of every inspection of every plant"). Most importantly, in Acito, the defendants made no statement denying the existence of any FDA communications regarding deficiencies at the facility.

Indeed, that distinction makes all the difference here. Even if, taking into account the seriousness of the observations contained in the September 2016 483 Letter, the Company was under no general affirmative obligation to disclose the letter, the statements at the three health care conferences contained material omissions. While Defendants may not have had an affirmative obligation "to disclose all material, nonpublic information" about the various FDA inspections and 483 letter observations it received, once Grenfell-Gardner "cho[se] to speak" regarding the Company's lack of 483 letters, he had a "duty to be both accurate and complete," and he was not. Plumbers' Union Local No. 12 Pension Fund, 753 F. Supp. 2d at 180 (quoting Caiola, 295 F.3d at 331). Defendants recognize that an omission is also

[13] Although the October 2017 483 Letter issued after the challenged statements, the Court notes that the number of observations increased slightly from five to six.

actionable where it was "so integral to an affirmative statement that it rendered a statement misleading by its absence." (Motion at 1.) Grenfell-Gardner told audiences at three separate health care conferences that Teligent had received no 483 Letters. The fact that Teligent had in fact received such letters renders those statements both manifestly false and misleading.

Next, in their Reply, Defendants argue that Oklahoma Police has taken Grenfell-Gardner's statements out of context, and that he was referring to the FDA's lack of 483 letter observations specifically during the Company's last three cGMP audit inspections; in contrast, the September 2016 483 Letter was issued in connection with the BIMO program. Defendants argue that BIMO inspections are drug-specific and more narrowly focused than cGMP inspections, which the FDA conducts regularly, approximately every two years. In particular, the September 2016 483 Letter referred to two specific studies for one drug, Acylcovir. Defendants note that when the FDA conducted its cGMP audit in October 2017, it referred to its previous inspection in January 2016, at which no deficiencies were observed. Since the FDA issued the September 2016 483 Letter in the interim, Defendants argue

that the distinction between cGMP audits and other kinds of inspections is clear and recognized by the FDA.[14]

Furthermore, Defendants point out that the Amended Complaint acknowledged the distinction between the two types of inspections and alleged that Grenfell-Gardner was "hair-splitting" by speaking only about cGMP inspections and not disclosing FDA observations from other types of inspections. Defendants suggest that Oklahoma Police omitted the distinction in the SAC to bolster its claim of falsity.

It is true, as Defendants argue, that some of Grenfell-Gardner's statements may be read in a way that would ignore completely the September 2016 inspection. In particular, at the Roth Capital Conference, he referred to the absence of 483 letter observations at the "last three audits over the past five years," with three audits in a period of five years, suggesting a cadence more aligned with cGMP audits as opposed to other kinds of inspections. (SAC ¶ 103.)

Grenfell-Garner's statement at the Deutsche Bank Health Care Conference lacked even this oblique reference to frequency; he referred only generally to the lack of 483 letter observations in "the audits conducted over the last five years." (SAC ¶ 118.) Similarly, at the Bank of America

[14] The October 2017 483 Letter resulted from this audit. (SAC ¶ 59.)

Merrill Lynch Healthcare Conference, Grenfell-Gardner referred to the lack of 483 observations "in the last three inspection cycles." (SAC ¶ 120.) Only in the accompanying PowerPoint presentation was it clear that Grenfell-Gardner was referring to the lack of 483 letter observations "in the last three cGMP inspections" and that the "last audit [was] in January 2016." (SAC ¶ 124.)

Nevertheless, for four reasons, the Court finds that Grenfell-Gardner's references to cGMP audits as opposed to other kinds of inspections do not change the Court's conclusion that Oklahoma Police has sufficiently alleged a material omission. First, it is unclear at this stage of the litigation how much weight should be ascribed to the PowerPoint versus the oral presentation; whether or not the additional information in the PowerPoint could cure the oral statement is a question better reserved for the evidentiary record on summary judgment. Second, the SAC does not describe any similar PowerPoint at the other two healthcare conferences. Third, even if there had been a similar PowerPoint presentation at the other conferences, the overall message could still have misled investors, given the presence of observations in the September 2016 483 Letter that related to cGMP compliance. Fourth, and finally, the PowerPoint

stated that the facility was cGMP compliant, when -- as discussed above -- its compliance was at least in doubt. In short, understanding Grenfell-Gardner's statements to omit reference to the September 2016 inspection does not necessarily render his statements more accurate and not materially misleading.

In addition to arguing that the Oklahoma Police is taking Grenfell-Gardner's statements out of context, Defendants argue that the audiences at health care conferences are "sophisticated" and "would have recognized this distinction" between the different kinds of inspections. (Reply at 2.) Given that -- as Defendants candidly acknowledge -- the FDA uses Form 483 letters "to report *all types* of inspectional observations," Grenfell-Gardner's statements were materially misleading, even if they were specific to a certain type of monitoring program and not cGMP audits. (Reply at 2 (emphasis added).) If Form 483 letters are used to report all types of inspectional observations, then it is wrong to claim there has been no such letter when the letter resulted from a BIMO inspection and equally wrong when the letter resulted from a cGMP audit (or any other kind of inspection), particularly when the BIMO inspection yielded observations that pertained to cGMP compliance. In the end, discovery may bolster Oklahoma

Police's claims on this front, or, indeed, it may not. But looking at the face of the SAC, as it must, the Court finds that Oklahoma Police has stated a claim for relief under the heightened pleading standards of Rule 9(b) and the PSLRA.

Finally, the Court addresses Defendants' claim that Oklahoma Police has "shift[ed] focus from the core allegations of the SAC" by arguing that the SAC states a claim based on Grenfell-Gardner's statements that Teligent had received no 483 letter observations. (Reply at 1-2.) The Court finds this point questionable at best. The SAC -- and in fact, even the Amended Complaint -- repeatedly alleges that Teligent concealed the 483 Letters. Indeed, the SAC relies on this concealment as a core allegation, despite what Defendants argue. Even if Defendants were right, the law does not require an allegation to be "core" to state a sufficient claim for relief. Oklahoma Police has alleged material omissions with particularity and that is enough to satisfy the Court's inquiry and the applicable standard.

B. SCIENTER

To establish scienter, Oklahoma Police must plead facts giving rise to a "strong inference" that Grenfell-Gardner acted with an intent to defraud. A strong inference "may be established either (a) by alleging facts to show that

defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." IKB Int'l S.A. v. Bank of Am. Corp., 584 F. App'x 26, 27-28 (2d Cir. 2014). To be considered "strong," the inference must be "at least as compelling as any opposing inference of nonfraudulent intent." Tellabs, Inc., 551 U.S. at 314.

Defendants argue that the SAC fails to allege scienter because Oklahoma Police "relies exclusively on Grenfell-Gardner's position as CEO to establish knowledge of the alleged regulatory and other problems." (Motion at 3.) Defendants cite to cases indicating that "accusations founded on nothing more than a defendant's corporate position are entitled to no weight." (October 25 Letter at 3 (quoting In re SuperCom Inc. Sec. Litig., No. 15 Civ. 9650, 2018 WL 4926442, at *30-31 (S.D.N.Y. Oct. 10, 2018)).) Defendants further argue that CW 1's allegations are insufficient to establish scienter, as they do not demonstrate that any Defendant's public statements were false or misleading, nor does the SAC allege that CW 1's concerns were discussed with or communicated to Grenfell-Gardner. (October 25 Letter at 3; Motion at 3.) Finally, Defendants argue that to the extent

Grenfell-Gardner was aware of FDA communications, those communications either did not undermine any statement by Defendants, or else were issued after the alleged misstatements and so cannot demonstrate scienter. (Reply at 3.)

The Court finds that Oklahoma Police has met its burden with respect to alleging scienter. Defendants' argument that the SAC "relies exclusively on Grenfell-Gardner's position as CEO to establish knowledge" is incorrect. (Motion at 3.) To the contrary, the SAC alleges that Grenfell-Gardner knew of all three of the 483 Letters.[15] With respect to the September 2016 483 Letter, the SAC alleges that the FDA addressed its subsequent February 21, 2017 Letter to Grenfell-Gardner, in which it warned that the observations in its September 2016 483 Letter "raise[d] concerns about the validity and integrity of the studies conducted at [Teligent's] study site." (SAC ¶ 56.) And with respect to the October 2017 483 Letter, the subsequent EIR stated that the FDA inspector personally met with Grenfell-Gardner during the inspection. (SAC ¶ 73.) More generally, the SAC alleges that Grenfell-Gardner's direct reports participated in other inspections,

[15] While the May 2019 483 Letter was received after the Class Period, the Court notes that the SAC alleges that this letter was addressed to Grenfell-Gardner. (SAC ¶ 74.)

and that both of the EIRs directed that correspondence should be addressed to Grenfell-Gardner. (SAC ¶¶ 148, 73.)

These factual allegations are sufficient. By asserting that FDA correspondence was addressed to Grenfell-Gardner, the SAC states with sufficient particularity the facts giving rise to a strong inference that Grenfell-Gardner knew of all three 483 letters. Indeed, where correspondence is addressed to a specific person, the inference that that person received the correspondence is strong. E.g., Yesh Music, LLC v. Amazon.com, Inc., 249 F. Supp. 3d 645, 653 (E.D.N.Y. 2017) (describing the mailbox rule). Thus, while the SAC also alleges more generally that Grenfell-Gardner was the CEO of a small company, and so would have been aware of the regulatory failures, such allegations are not necessary to sustain the Court's finding. Because the SAC adequately alleges that Grenfell-Gardner knew of all three 483 Letters and made public statements denying that they existed, the SAC thereby alleges that he "knew facts or had access to information suggesting that [his] public statements were not accurate." ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 199 (2d Cir. 2009). Such pleading is enough to raise a strong inference of scienter under the circumstantial evidence prong. See

Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc., 531 F.3d 190, 194 (2d Cir. 2008). And while the Court must consider competing inferences that may be drawn from Defendants' conduct, in accordance with the Supreme Court's decision in Tellabs, Inc., here, it finds no competing alternative inference that may be drawn from Defendants' conduct as strong as the inference of what would, at best, be characterized as recklessness.

C. LOSS CAUSATION

The Court turns next to loss causation. The parties dispute whether the SAC has demonstrated a causal link between Defendants' alleged misconduct and Oklahoma Police's economic harm. See Lentell, 396 F.3d at 172. Defendants argue that the purported corrective disclosures in November 2017 did not cure any prior misstatement or reveal any concealed information that Teligent had a duty to disclose, and also point out that Defendants have still not disclosed any of the 483 Letters, and so the SAC fails to allege loss causation to the extent it claims Teligent omitted the existence or contents of the 483 Letters. Oklahoma Police responds that the November 2017 corrective disclosures made clear that Teligent did not have the resources to properly respond to the FDA's observations, contrary to Teligent's public

statements. Oklahoma Police further notes that if Defendants could defeat loss causation by simply never disclosing the 483 Letters, they would be able to "impermissibly inoculate themselves" from misstatements. (Opposition at 3.)

The Court finds that the SAC sufficiently pleads that the loss Oklahoma Police claims was foreseeable and caused by the materialization of the concealed risk. The chain of alleged causation here is clear: the 483 Letters contained observations related to Teligent's failure to comply with FDA regulations; the November 6, 2017 corrective disclosure -- issued the same exact day that Teligent responded to the October 2017 483 Letter -- told of "pipeline and manufacturing problems" that "were the precise and foreseeable consequences of Teligent's regulatory compliance failures" (SAC ¶¶ 139, 163), and the next day, Teligent's stock price dropped precipitously. (See also Opposition at 1 (arguing that by "concealing [the September 2016] 483 Letter, Grenfell-Gardner also concealed deep-seated regulatory failures described therein").) Furthermore, Oklahoma Police plausibly alleges that the "timing and magnitude of [the] precipitous decline in Teligent's stock price . . . negates any inference that the loss suffered by investors was caused by changed market conditions, macroeconomic or industry factors, or other facts

unrelated to Defendants' fraudulent conduct." (SAC ¶ 165.) Oklahoma Police is not required to meet a heightened pleading standard for loss causation; it must provide Defendants only "some indication of the loss and the causal connection that the plaintiff has in mind." Freudenberg v. E*Trade Fin. Corp., 712 F. Supp. 2d 171, 202 (S.D.N.Y. 2010) (quoting Dura Pharm., Inc., 544 U.S. at 346-47). The allegations in the SAC are more than sufficient to meet this standard.

Finally, it is immaterial that, as Defendants pointed out, they *still* have not disclosed the existence of the 483 Letters. (See SAC ¶ 91.) From a policy perspective, continuing to conceal the 483 Letters should not shield a company from liability. From a practical perspective, Oklahoma Police sufficiently alleges that the November 2017 disclosure revealed issues discussed in the 483 Letters, even if at a higher level of generality. And from a purely legal perspective, Defendants point to no controlling case law that suggests that a defendant's refusing to disclose a material fact can defeat an allegation of loss causation. Defendants' arguments are without merit.

D. SECTION 20(A)

The Court turns last to Oklahoma Police's claim against Grenfell-Gardner pursuant to Section 20(a) of the Exchange

Act. To state a claim for derivative liability under Section 20(a), a plaintiff must show "(1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." ATSI Commc'ns, 493 F.3d at 108. Oklahoma Police has sufficiently alleged the first two elements by stating a claim for relief under Section 10(a) and Rule 10b-5 and sufficiently alleging Grenfell-Gardner's control of Teligent. (SAC ¶ 192 (alleging Grenfell-Gardner's "direct and supervisory involvement in the day-to-day operations of the Company" and responsibility for preparing "press releases and SEC filings" as well as "statements to the market in . . . conference calls").)

The Court finds that the third element is easily met here, as Grenfell-Gardner himself made the challenged statements at the three healthcare conferences discussed above. Thus, Oklahoma Police has stated a claim under Section 20(a) of the Exchange Act.

IV. ORDER

Accordingly, for the reasons stated above, it is hereby

ORDERED that the motion so deemed by the Court as filed by defendants Teligent, Inc. and Jason Grenfell-Gardner (Dkt.

Nos. 40 and 41) to dismiss the Second Amended Complaint of plaintiff Oklahoma Police Pension Fund and Retirement System (Dkt. No. 39) pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure is **DENIED IN PART** and **GRANTED IN PART** as set forth above. And it is further hereby

ORDERED that the parties meet and confer and prepare a proposed Case Management Plan to be submitted to the Court within twenty days of the date of this Order.

SO ORDERED.

Dated: New York, New York
17 June 2020

Victor Marrero
U.S.D.J.